DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Medtronic Sofamor Danek USA, Incorporated
Ms. Lila Joe
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tenseness 38132

December 1, 2014

Re: K142591
Trade/Device Name: CD HORIZON® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ
Dated: September 12, 2014
Received: September 15, 2014

Dear Ms. Joe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142591

Device Name

CD HORIZON(R) Spinal System

Indications for Use *(Describe)*

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/ attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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CD HORIZON® Spinal System
510(k) SUMMARY
November 2014

I. Submitter

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901)396-3133

Contact

Lila Joe
Principle Regulatory Affairs Specialist

Date Prepared

November 26, 2014

II. Device

Name of Device

CD HORIZON® Spinal System

Classification Name

Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, and Pedicle Screw Spinal System (21 CFR 888.3050, 888.3060 and 888.3070)

Classification

Class III (Pre-amendment)

Product Codes

OSH, NKB, MNH, MNI, KWP, &KWQ

III. Predicates

CD HORIZON® Spinal System
K042025 (S.E. Aug 25, 2004),
K031655 (S.E. Jun 27, 2003),
K052187 (S.E. Aug 22, 2005), and
K141494 (S.E. Aug 08, 2014) - primary predicate

IV. Product Description

The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, staples, and connecting components, as well as implant components from other Medtronic spinal systems which can be rigidly locked into a variety of configurations with each construct being tailor-made for the individual case.

A subset of CD HORIZON® Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5mm to 6.35mm), hooks, screws,

CROSSLINK® Plates and connecting components. Similarly to the CD HORIZON® implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The purpose of this submission is to add additional components to the CD HORIZON® Spinal System, specifically multi-axial screws (MAS), fixed angled Screws (FAS), and break-off set screws (BOSS).

The subject devices are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and /or sacral spine. The multi-axial screw is a polyaxial screw, which allows the screw to be angled in any direction. This feature makes it easier for the surgeon to implant rods. The fixed angle screw is a monoaxial screw, which is used when the surgeon needs a more rigid construct. The break-off set screw is used with both the multi-axial screw and fixed angle screw to tighten the rod into the screw head.

The subject devices are manufactured from titanium alloy or titanium alloy/ commercially pure titanium, per *ASTM F136-13 – Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications* and *ASTM F67-13 - Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700),* which are identical to the materials used to manufacture the predicate devices.

The subject multi-axial screws, fixed angle screws, and break-off set screws are implants that are single use only. The subject multi-axial screws, fixed angle screws, and break-off set screws are provided non-sterile and steam sterilized by the hospital. Additionally, the subject multi-axial screws and break-off set screws are also provided sterile by gamma irradiation.

V. Indications for Use:

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

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With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis,

neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

VI. Comparison of Technological Characteristics

The subject CD HORIZON® Spinal System has the same indications, intended use, fundamental scientific technology and material as the previously FDA cleared predicates. CD HORIZON® Spinal System multi-axial screws, fixed-angled screws, and break-off set screws cleared in K042025 (S.E. Aug 25, 2004), K031655 (S.E. Jun 27, 2003), and K052187 (S.E. Aug 22, 2005), respectively. At a high level, the subject and predicate devices are based on the following same technological elements:

- Implanted into the patient
- Used with rods, hooks, cross-links, and other instrumentation to build a construct
- The subject devices are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and /or sacral spine.

VII. Performance Data

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for the subject CD HORIZON® Spinal System multi-axial screws, fixed angled screws, and break-off set screws was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing" issued April 23, 2013.

The subject multi-axial screws, fixed angle screws, and break-off set screws are permanent implants and will be classified as "Implant Devices - Tissue/bone - C Permanent (>30 days)" according to FDA's Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, Biological Evaluation Method Devices Part 1: Evaluation and Testing.

The subject devices are manufactured from titanium alloy or titanium alloy/ commercially pure titanium, per *ASTM F136-13 – Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications* and *ASTM F67-13 - Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700),* which are identical to the materials used to manufacture the predicate devices.

Titanium Alloy and Commercially Pure Titanium have a long history of safe and effective use in predicate spinal implants. Therefore, biocompatibility testing is not required.

Mechanical Testing

In accordance with, *Guidance for Industry and FDA Staff - Spinal System 510(k)'s,* Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices.

Design verification testing was completed in accordance with *ASTM F1717 - Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*, and *ASTM F1798 – "Standard Guide to Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.* The tests completed were:

- Axial Grip
- Axial Torsion
- Flexion Extension Static Testing
- Flexion Extension Fatigue
- Construct Static Compression Bending
- Construct Static Torsion
- Construct Compression Bending Fatigue

The subject devices met the pre-determined acceptance criteria for all tests.

VIII. Conclusions

A risk analysis was completed and design verification testing was completed in accordance with ASTM F1717 and ASTM F1798. Based on the test results and additional supporting information provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the legally marketed predicate devices, including the predicate CD HORIZON® Spinal System.